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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/628,472	07/31/2000	Paul K. Wolber	10003511-1	5543

22878 7590 09/22/2003

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EXAMINER

FORMAN, BETTY J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 09/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/628,472

Applicant(s)

WOLBER ET AL.

Examiner

BJ Forman

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 18 August 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: see continuation of Advisory Action.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☒ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see continuation of Advisory Action.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 1-15.

Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☒ Other: continuation of Advisory Action

Continuation of Advisory Action

The amendments submitted 18 August 2003 in a response After-Final rejection will not be entered because they raise issues not previously considered. The amendments remove the "primer extension" limitation and define the nucleic acid mixture as comprising a mixture of "single stranded" nucleic acids. The amendments change the scope of the instant claims. Because the limitations have not been previously searched and/or considered, they would require further search and consideration.

Response to Applicant's Comments

Regarding the rejection under 35 U.S.C. 112, first paragraph, new matter: Applicant argues that the specification's teaching of linear PCR and SDA which do not require two primers and further teaching of in vitro transcription known to produce solution product supports the recitation "reaction that produces a solution phase product comprising a mixture of nucleic acids of differing sequence". While Applicant has provided support for single primer reactions, linear PCR, SDA and primer-less in vitro transcription, Applicant has not provided support for the claimed "solution phase product comprising a mixture of nucleic acids of differing sequence". The object and rejection over new matter are maintained.

Regarding the rejection over Wolber et al: Applicant relied on the Declaration filed under 37 C.F.R. 1.132 to overcome the rejection.

The Declaration filed on 18 August 2003 under 37 CFR 1.132 has been considered but is ineffective to overcome the Wolber et al reference.

The declaration states that 1) Wolber is a co-inventor of the instant application; 2) Wolber is a co-inventor of U.S. Patent No. 6,235,483; and 3) Wolber conceived and invented the

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subject matter disclosed but not claimed in the '483 patent that is subject of the claims of the present application.

The declaration is insufficient for two reasons. First, the declaration states that "I conceived and invented the subject matter disclosed but not claimed in the cited patent". Which means that, Wolber is the inventor of the disclosed subject matter and Wolber, Kincaid, Amorese, Ilsley, and Atwell are inventors of the instantly claimed subject matter. Therefore, the subject matter disclosed in the patent and the instantly claimed subject matter have different inventive entities i.e. they are "by another" and therefore, the rejection is still proper under 35 U.S.C. 102(e). Second, the declaration raises new issues of inventorship for the instantly claimed invention because Wolber states "I conceived and invented the subject matter.....that is the subject of the claims of the present application".

Regarding the rejection over Bulyk: Applicant argues that as amended the claims are drawn to a mixture of single stranded nucleic acids in contrast to Bulyk who teaches double stranded nucleic acids. The argument has been considered but is deemed moot in view of the fact that the argument addresses the unentered amendments. Furthermore, if entered, it is unlikely that the amendment would overcome the rejection over Bulyk because the claim is drawn to a "product comprising a mixture of single stranded nucleic acids". The open claim language "comprising" encompasses double stranded nucleic acids which include single stranded nucleic acids.

Regarding the rejection over Lipshutz in view of Bulyk: Applicant argues that one of ordinary skill in the art would not have been motivated to combine the teaching of Lipshutz

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with that of Bulyk because the method of Lipshutz requires two constant domains as primer sites. The argument has been considered but is not found persuasive because as stated in the final office action, Bulyk et al teach a method similar to that of Lipshutz wherein the 5' sequence of the probe is variable and whereby template is amplified via primer extension using a single primer to thereby replicate templates of long length with accuracy and efficiency (Abstract and page 573, right column first full paragraph). Therefore one of ordinary skill in the art would have been motivated to combine the teachings to thereby replicate templates of long length with accuracy and efficiency (Bulyk, Abstract and page 573, right column first full paragraph).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



BJ Forman, Ph.D.
Primary Examiner
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September 16, 2003